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Proposed Re-evaluation Decision PRVD2016-19

Antisapstain and Joinery Uses of Propiconazole

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Background

This document forms part of a wider assessment of health and environmental risks of the active ingredients used in antisapstain and joinery treatments.

In 2004, the Pest Management Regulatory Agency (PMRA) completed a re-evaluation of the occupational risks for the antisapstain uses of three antisapstain active ingredients: 2-(thiocyanomethylthio) benzothiazole (TCMTB), copper-8-quinolinolate (copper-8), and disodium octaborate tetrahydrate (boron). The occupational exposure and risk assessments were conducted for workers at lumber processing facilities such as sawmills. The re-evaluation decision (RRD2004-08) identified the need for additional data to refine the occupational risk assessments and required that a product stewardship program (with follow-up monitoring) be implemented for all registered antisapstain chemicals to reduce exposure to workers. In addition, RRD2004-08 indicated that an assessment of the environmental risks of antisapstain products would be communicated in separate documents.

In response to the 2004 decision, the registrants of antisapstain products, the Sapstain Industry Group, developed a product stewardship program, referred to as the Exposure Reduction Program (ERP). This program was approved by PMRA, implemented for all antisapstain products and follow-up occupational exposure field monitoring was conducted. The ERP included additional personal protective equipment and engineering controls, which have shown to be effective in reducing worker exposure.

There are currently five active ingredients registered as joinery wood preservatives. These active ingredients are: boron, DDAC, iodocarb, propiconazole and tebuconazole. Considering that the occupational exposure scenarios for antisapstain and joinery uses are similar, and in the interest of efficiencies and consistency in decision making, occupational risk assessments were also conducted for all joinery products using the Sapstain Industry Group's follow-up field monitoring exposure data.

Altogether seven active ingredients registered as antisapstain and/or joinery wood preservatives required updated health and environmental risk assessments. These active ingredients are: TCMTB, copper-8, boron, DDAC, iodocarb, propiconazole, and tebuconazole. The occupational risk assessments for these seven antisapstain and joinery active ingredients have been updated using current use information, current toxicology endpoints and the follow-up field monitoring exposure data. The environmental risk assessments have been conducted using available data and information.

This document addresses the health and environmental risk assessments for the antisapstain and joinery uses of propiconazole. The re-evaluation of the antisapstain and joinery uses of the remaining active ingredients listed above will be communicated in separate documents.

Overview

Proposed Re-evaluation Decision for Antisapstain and Joinery Uses of Propiconazole

The PMRA has completed the health and environmental risk assessments for the antisapstain and joinery uses of propiconazole. Under the authority of the *Pest Control Products Act*, the PMRA is proposing continued registration of the antisapstain and joinery uses of propiconazole in Canada.

An evaluation of available scientific information found that the antisapstain and joinery uses of propiconazole products are not expected to pose risks of concern to human health or the environment when used according to the proposed revised label directions. As a requirement for the continued registration of antisapstain and joinery products containing propiconazole, new risk-reduction measures are proposed.

This proposal affects the joinery and antisapstain end-use products containing propiconazole registered in Canada. Once the final re-evaluation decision is made, the registrant will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for propiconazole and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of propiconazole.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[2] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use of, or exposure to, the product under its conditions or proposed conditions of registration.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

The Act also requires that products have value[3] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of potentially sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management section of Health Canada's website.

For more details on the information presented in this overview, please refer to the Science Evaluation of this consultation document.

What is Propiconazole?

Propiconazole is a triazole-based fungicide that is used to control fungi. Propiconazole is registered for use in antisapstain and joinery products. In addition to its uses as an antisapstain and for joinery, propiconazole is also registered to control fungi in agriculture and turf.

Antisapstain products are wood preservatives used to prevent the growth of staining fungi in freshly cut lumber. They are applied to freshly-cut wood by dipping or spraying to achieve short-term (months) protection against staining fungi.

Wood products that have been manufactured into items such as windows and doors are referred to as joinery or millwork. These items are often used in above-ground settings where they are subject to moderate decay conditions. For this reason, wooden windows and doors are typically protected with a joinery wood preservative to prevent the growth of decay fungi and increase the service life. Unlike antisapstain treatments, which are applied to lumber for short-term protection against aesthetic damage, joinery preservatives provide long-term decay protection to wood that does not require the degree of protection provided by heavy-duty wood preservation.

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[3] "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

Health Considerations

Can Approved Uses of Propiconazole Affect Human Health?

Antisapstain and joinery products containing propiconazole are unlikely to affect your health when used according to revised label directions.

Potential exposure to propiconazole may occur through the dermal and inhalation routes, when workers are handling and applying antisapstain and joinery products containing propiconazole or when handling the treated wood. When assessing health risks, two key factors are considered: the levels at which no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

In laboratory animals, propiconazole was of low to slight acute oral toxicity, low acute dermal toxicity and slightly toxic by the inhalation route. It was minimally irritating to the eye, mildly irritating to skin and a skin sensitizer.

Registrant-supplied short-, and long-term (lifetime) animal toxicity tests were assessed for the potential of propiconazole to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment included effects on the liver, malformations in developing young, and gastrointestinal irritation. The risk assessment protects against the above-noted effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occur in animal tests.

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern.

There are currently no registered residential uses of propiconazole antisapstain and joinery products. As such, a risk assessment for a residential handler was not required.

Occupational Risks to Mixer/Loader/Applicator and Postapplication Workers

Occupational risks are not of concern when used according to the revised label directions.

Health risks to handlers are not of concern for all scenarios. Based on the updated personal protective equipment (PPE) required as a result of the ERP for Antisapstain Chemicals (see

section 3.4.3 of the science evaluation), health risk estimates associated with mixing, loading, and applying and during handling of treated wood and joinery products exceeded target dermal margins of exposure (MOEs) and are not of concern. Inhalation exposure was shown to be very low for the majority of workers and is mitigated by the use of a NIOSH-respirator for specific job tasks where there is potential for inhalation exposure, as described in the ERP. Current product labels that do not include all of the required elements of the personal protective equipment will be updated to conform to the ERP.

Postapplication risks are not of concern.

Postapplication exposure through contact with dried wood is not anticipated as antisapstains are designed to prevent the growth of staining fungi in freshly cut lumber during storage and transit and not for long-term wood protection in residential or commercial areas. Similarly, exposure to consumers from contact with treated wood is also considered to be minimal.

Joinery wood is intended for use in millwork, window and door frames and other above ground non-structural decorative exterior wood such as soffits and fascia. Significant human exposure is not expected for this type of wood.

Environmental Considerations

What Happens When Propiconazole Is Introduced Into the Environment?

When used as an antisapstain according to the proposed label directions, propiconazole is not expected to pose risks of concern to the environment.

Antisapstains, such as propiconazole, may enter the environment by leaching from treated wood stored at treatment facilities. It may reach the aquatic environment through runoff into nearby waterbodies during rainfall events. Exposure to land organisms and their habitats is expected to be negligible. Propiconazole is broken down by microbes present in soil and is not expected to persist for long periods of time. Propiconazole mixes readily in water but is expected to move out of water and into sediments in aquatic environments where it is slowly broken down by microbes and may persist. Propiconazole is not expected to be found in air and is not expected to accumulate in the tissues of organisms or in the environment. Propiconazole has medium to low potential to move through soil depending on the amount of organic matter in the soil and has low potential to seep into groundwater. Propiconazole is toxic to fish and aquatic invertebrates if they are exposed to sufficiently high levels. However, the mitigation measures required on the label are expected to ensure minimum exposure to aquatic organisms.

Treated wood joinery products are not subject to significant leaching. Any leaching of joinery preservative that does occur, should be limited to the area around the building in which they were installed. Therefore, due to limited environmental exposure, no quantitative environmental risk assessment was conducted for the joinery uses of propiconazole. Furthermore, as most joinery active ingredients are also antisapstain active ingredients, the environmental risk assessment for the antisapstain use of propiconazole would be expected to cover any environmental risks posed by joinery products.

Value Considerations

What is the Value of Propiconazole in Antisapstain Treatment?

Propiconazole is one of several active ingredients currently registered in Canada for use in antisapstain products. Antisapstain products are wood preservatives used to prevent the growth of staining fungi in freshly cut lumber. These pigmented fungi consume the readily available sugars and starches as they grow throughout the sapwood. While these sapstain fungi do not reduce the strength of the wood, the aesthetic damage done can result in significant economic losses in terms of the lumber being unmarketable or reduced in value.

What is the Value of Propiconazole in Joinery Treatment?

Propiconazole is one of five active ingredients currently registered in Canada for use in joinery products. Joinery products are wood preservatives used to treat products that have been machined or milled, such as window frames or doors. While these window frames and doors tend to be sheltered from excessive rains, they are still susceptible to fungal decay. Treatment with joinery products containing propiconazole inhibits the growth of decay fungi and extends the service life of wooden joinery components.

Proposed Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. Following these directions is required by law. As a result of the re-evaluation of antisapstain and joinery uses of propiconazole, the PMRA is proposing further risk-reduction measures in addition to those already identified on propiconazole product labels.

Additional Key Risk Reduction Measures

Human Health

To protect workers, additional general hygiene statements and personal protective equipment are required on all propiconazole antisapstain and joinery product labels.

Environment

In order to minimize the amount of propiconazole entering aquatic environments, wood treatment facilities for antisapstain products are to be equipped with drip pads (where wood is allowed to sit for a short drying period immediately after treatment) that are roofed and paved.

Standard precautionary label statements are required to identify environmental hazards and prevent runoff from treatment facilities to waterbodies.

Next Steps

Before making a final re-evaluation decision on the antisapstain and joinery uses of propiconazole, the PMRA will consider any comments received from the public in response to this consultation document.[4] A science-based approach will be applied in making a final decision on propiconazole. The PMRA will then publish a Re-evaluation Decision[5] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA response to these comments.

4 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

5 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

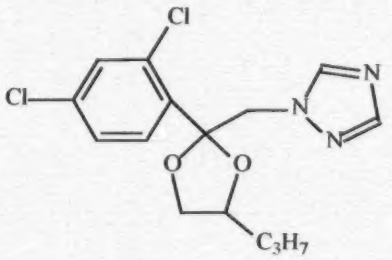
1.0 Introduction

Propiconazole is a triazole-based fungicide that is used to control fungi. The mode of action is by inhibition of fungal ergosterol biosynthesis that is essential for cell wall formation.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

A review of the chemistry was previously published in PRVD2011-02.

2.1 Identity of the Technical Grade Active Ingredient

Common Name		Propiconazole
Function		Fungicide
Chemical Family		Triazole
Chemical Name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	(RS)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole
2	**Chemical Abstracts Service (CAS)**	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
CAS Registry Number		60207-90-1
Molecular Formula		$C_{15}H_{17}Cl_2N_3O_2$
Structural Formula		
Molecular Weight		342.22 amu
Registration Number and Purity of the Technical Grade Active Ingredient (%)		22434 - 95.0% 27530 - 93.0% 22474 - 93%

Based on the manufacturing process used, contaminants of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties

Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	5.6 × 10-2 mPa
Ultraviolet (UV)/visible spectrum	Not expected to absorb at λ ›300 nm (maximum at 269 nm)
Solubility in water at 20°C	100 ppm
n-Octanol/water partition coefficient	Log $K_{ow} \geq 3$

2.3 Description of Registered Propiconazole Uses

Appendix I lists the antisapstain and joinery propiconazole products that are registered under the authority of the *Pest Control Products Act*.

Propiconazole is a fungicide registered in Canada to control a variety of fungi. When used as an antisapstain, it is applied to freshly-cut wood by dipping or spraying to achieve short-term protection against staining fungi. Joinery products may be applied by dipping, spraying, double vacuum treatment or flow/flood coating.

Propiconazole has been registered in Canada for antisapstain use since 2000. Propiconazole has been shown to be effective in preventing sapstain on freshly treated lumber for a period of 2-6 months. Propiconazole has been registered in Canada for joinery use since 1995. Propiconazole has been shown to be an effective joinery preservative.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A review of the toxicity studies conducted with propiconazole was previously published in PRVD2011-02, which included the re-evaluation of the non-antisapstain uses of propiconazole.

Oral metabolism rat studies with radiolabelled propiconazole showed that about 78% of radioactivity was excreted in the urine and faeces within 24 hours. Recovery of radioactivity was almost complete by six days (28-46% in faeces and 53-67% in urine), with the highest levels found in the liver, blood, kidneys and lungs. Propiconazole was extensively metabolized and did not bio-accumulate in the body.

Propiconazole is of low to slight acute oral toxicity in mice, rats and rabbits, low acute dermal toxicity in rats and slightly toxic by the inhalation route in rats. It is minimally irritating to the eye of rabbits, mildly irritating to rabbit skin and a skin sensitizer in guinea pigs.

In rats and mice, the most prominent findings in repeat-dose studies were effects on the liver. Other effects included decreased body weight, organ weight changes, clinical signs of toxicity, and alterations in clinical chemistry parameters. Following long-term dosing in rats, additional effects were noted in females including atrophy of the exocrine pancreas. In repeat-dose studies with beagle dogs, findings were limited to the gastrointestinal tract, and were indicative of local irritation, rather than systemic toxicity.

Decreased pup body weights and decreased pup survival were observed in the 2-generation rat reproductive toxicity study at a dose that was also toxic to the adults. In the developmental toxicity studies with rabbits, there was evidence of developmental toxicity, including decreased fetal weight and increased incidences of delayed ossification, cleft palate, abortions, fetal resorptions and fully formed 13th ribs, at a dose that also caused maternal toxicity. In developmental toxicity studies in rats, findings included increased incidence of delayed ossification, rudimentary ribs and cleft palate, all of which occurred at a dose that did not cause adverse effects in maternal animals.

There was no evidence of carcinogenicity in the rat. In a 2-year mouse study, there was an increased incidence of hepatocellular adenomas and carcinomas in both sexes at the high dose, although the increases in these lesions were slight in females. In an 18-month study, there was a statistically significant increase in the incidence of hepatocellular adenomas and combined adenomas and carcinomas at the high dose compared to the concurrent controls. Propiconazole is considered to have liver tumour promoting effects (increased liver weights, hepatocellular hypertrophy, hepatocellular proliferation and hepatocellular adenomas/carcinomas) that are similar to those induced by phenobarbital. A threshold approach was used to assess cancer risk for propiconazole.

Evidence for neurotoxicity was limited to clinical signs of toxicity generally observed at doses causing overt systemic toxicity. Some evidence of effects on the endocrine system was noted, but generally at higher doses and/or in conjunction with other signs of systemic toxicity.

3.1.1 *Pest Control Products Act* Hazard Characterization

For assessing risks from potential residues in food or from products used in and around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of and toxicity to infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, the database for propiconazole contains a 2-generation reproductive toxicity study in rats and developmental toxicity studies in rats and rabbits. Additional information regarding reproductive toxicity was also available in the published literature.

With respect to potential prenatal and postnatal toxicity, no evidence of increased sensitivity of the young was observed in the 2-generation reproductive toxicity study in rats. Decreased pup body weights and decreased pup survival were observed at a dose that was also toxic to the adults. Published studies noted additional toxic effects in offspring at a dose similar to the lowest observed adverse effect in the 2-generation study (altered estrous cycles, increased serum testosterone levels and testes weights), or at a higher dose (increased anogenital distance in males).

In the developmental toxicity studies with rabbits, there was evidence of developmental toxicity, including decreased fetal weight and increased incidences of delayed ossification, cleft palate, abortions, fetal resorptions and fully formed 13th ribs, at a dose that also caused maternal toxicity. In developmental toxicity studies in rats, findings included increased incidences of delayed ossification, rudimentary ribs and cleft palate, all of which occurred at a dose that did not cause adverse effects in maternal animals.

In the rat developmental toxicity studies, fetal effects, including a serious endpoint (cleft palate malformation), were observed in the absence of adverse effects on maternal animals. On the basis of this information, the full 10-fold *Pest Control Products Act* factor was retained for scenarios for which this endpoint was relevant. For all other scenarios, the *Pest Control Products Act* factor was reduced to onefold since there were no residual uncertainties with respect to the completeness of the data, or with respect to potential toxicity to infants and children.

3.2 Determination of Acceptable Daily Intake

Not applicable for antisapstain and joinery uses.

3.3 Determination of Acute Reference Dose

Not applicable for antisapstain and joinery uses.

3.4 Occupational and Non-Occupational Exposure and Risk Assessment

Occupational and non-occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive sub-population. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

3.4.1 Toxicological Endpoint Selection for Occupational Risk Assessment

Occupational exposure to propiconazole is characterized as intermittent long-term in duration and is predominately by the dermal route.

For long-term dermal:

For long-term dermal exposure, the no observed adverse effects level (NOAEL) of 30 mg/kg bw/day from the rat developmental toxicity study was selected for use in risk assessment. In this study, effects on the fetus included increased incidences of rudimentary ribs, non-ossified sternebrae and cleft palate. The available short-term dermal toxicity studies did not address the endpoint of concern (cleft palate). The target MOE is 1000, which includes uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability, and an additional 10-fold to protect pregnant female workers from potential effects in the developing fetus.

Use of this NOAEL provides a margin of 3600-fold to the dose at which liver tumours were observed (in the 18-month mouse study).

Table 1 Toxicology Endpoints for Use in Health Risk Assessment for Propiconazole

Exposure Scenario	Study	Point of Departure and Endpoint	Target MOE
Long-term dermal	Developmental toxicity study in rats	NOAEL = 30 mg/kg bw/daybased on malformations in the absence of maternal toxicity	1000
Cancer	Threshold approach for cancer risk assessment.		

3.4.2 Dermal Absorption

The estimated dermal absorption is based on a chemical-specific in vivo rat dermal absorption study. A dermal absorption value of 29% was used in estimating the systemic dose from dermal exposure to propiconazole for the risk assessment.

3.4.3 Occupational Exposure and Risk Assessment

The Sapstain Industry Group conducted passive dosimetry worker exposure studies to measure the potential exposure of sawmill workers that are exposed to antisapstain chemicals. The complete study was divided into four phases: Phase I identified an appropriate surrogate chemical; Phase II monitored workers to determine job tasks with a potential for exposure to antisapstain chemicals (handling wet treated lumber, handling dry treated lumber, maintenance (including clean-up) and operating diptanks); Phase III measured workers exposure to those job tasks; and Phase IV measured worker's exposure following the implementation of a Product Stewardship and Exposure Reduction Program (ERP) for the job tasks that demonstrated the highest exposure during Phase III. The workers with the highest potential for exposure included clean-up and maintenance workers, and pilers handling freshly treated wood. The ERP also identified areas in sawmills that would benefit from additional mitigation measures to reduce antisapstain chemical exposure, including engineering controls for application systems, instruction on safe handling procedures and proper personal protective equipment, and education on the health and safety properties of the antisapstain chemicals. The ERP was shown to reduce exposure for workers handling antisapstain chemicals.

Exposure to workers in a joinery mill is not expected to be underestimated by the Sapstain Industry Group antisapstain exposure study, which measured exposure during treatment by diptank and spraybox systems and while handling treated wood.

3.4.3.1 Occupational Antisapstain and Joinery Exposure and Risk Assessment

Workers can be exposed to propiconazole while treating wood, handling treated wood and during clean-up, maintenance and repair activities. Exposure is expected to be long-term in duration and to occur primarily via the dermal route. Inhalation exposure was demonstrated to be very low for the majority of worker activities in the Phase III of the Sapstain Industry Group study and was not assessed during Phase IV. In addition, a NIOSH-respirator is required during clean-up, maintenance and repairs, and if working in areas that are not well ventilated, in order to reduce potential inhalation exposure, as defined in the ERP.

Dermal exposure was estimated by combining the unit exposure values from the surrogate antisapstain worker exposure study with the amount of product handled per day and the dermal absorption value. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

The results of the health risk assessment for sawmill workers exposed to antisapstain or joinery products containing propiconazole are shown in Table 3.4.3.1. Calculated MOEs exceeded the target MOE and no health risks of concern were identified for sawmill workers wearing the appropriate personal protective equipment as outlined in Appendix III.

Table 3.4.3.1 Propiconazole Exposure Assessment for Sawmill Workers Exposed to Antisapstain and Joinery Products

Tasks	Unit Exposure (µg / mg/mL)	Max Rate[1] (mg/mL)	Daily Exposure (mg/kg bw/day)	MOE[2]
SIG Phase IV				
Pilers	493.7	10	0.01790	1677
Clean-up Crew	203.1	10	0.007362	4075
Maintenance Workers	401.4	10	0.01455	2062

TSC = Treatment solution concentration, MOE = Margin of exposure

[1] The maximum treatment solution rates of all propiconazole products is shown as the most conservative scenario.

[2] Dermal MOEs are based on a NOAEL of 30 mg/kg bw/day and a dermal absorption value of 29%. Target MOE is 1000. MOE = NOAEL/ (Unit Exposure (µg/kg ai) * Application Rate * Dermal Absorption / Body Weight (80 kg)).

3.4.4 Postapplication Worker Exposure and Risk Assessment

Postapplication exposure is not anticipated, as antisapstains are designed to prevent the growth of staining fungi in freshly cut lumber during storage and transit and not for long-term wood protection in residential or commercial areas.

Joinery wood is intended for use in window and door frames and other above ground non-structural decorative exterior wood such as soffits and fascia. Additionally, joinery wood is

often painted or covered with vinyl or aluminum or other material prior to being sold in the market. Significant human post application exposure is not expected for this type of wood.

Furthermore, no health risks of concern were identified for workers handling freshly treated wood (wet or dry) in the sawmill whose exposure is expected to be greater than for workers handling of treated wood or joinery products after it has left the sawmill.

3.4.5 Non-Occupational Exposure and Risk Assessment

Non-occupational or residential risk assessment involves estimating risks to the general population, including children and youths, during or after pesticide application. There are no registered domestic class antisapstain products for propiconazole. Residential exposure to individuals contacting wood treated with propiconazole for antisapstain or joinery uses is not expected to result in health risks of concern.

3.4.6 Bystander Exposure

Bystander exposure is not anticipated, as propiconazole containing antisapstain products are designed to prevent the growth of staining fungi in freshly cut lumber during storage and transit and not for long-term wood protection in residential or commercial areas.

Joinery wood is intended for use in window and door frames and other above ground non-structural decorative exterior wood such as soffits and fascia. Additionally, joinery wood is often painted or covered with vinyl or aluminum or other material prior to being sold in the market. Significant human exposure is not expected for this type of wood. Additionally, joinery wood is often painted or covered with vinyl or aluminum or other material prior to being sold in the market.

Furthermore, no health risks of concern were identified for workers handling freshly treated wood (wet or dry) in the sawmill whose exposure is expected to be greater than for bystanders handling treated wood or joinery products after it has left the sawmill.

Therefore, health risks to bystanders are not of concern.

3.5 Incident Reports

As of 26 April 2016, the PMRA had received 17 human and two domestic animal incident reports involving propiconazole. Most incidents involved fungicides used in agriculture that also involved other active ingredients. A wood preservative product was listed in one incident.

Eight human incidents involving 16 people were determined to be related to the reported exposure scenario. These cases were either minor (14) or moderate (2) in severity. A wide range of symptoms were described including nausea, cough, headache, sore throat, skin irritation, breathing difficulties, eye irritation and loss of coordination. Exposure to propiconazole mainly occurred as a result of drift from the application site. Product application, pesticide spill and contact with freshly treated lumber were other reported scenarios.

There were two domestic animal incidents involving propiconazole reported to the PMRA. One dog and three horses were affected in these incidents. In both incidents, there was insufficient information involving exposure to assess if the described animal symptoms were related to the reported pesticide.

These incident reports were considered in this evaluation and did not affect the risk assessment.

No label changes resulting from these incident reports are considered necessary at this time.

3.6 Cumulative Assessment

Cumulative assessment takes into consideration non-occupational exposures (exposure via dietary, drinking water and residential use) to multiple pesticides that share a common mechanism of toxicity. As there are no domestic class registrations for propiconazole as an antisapstain, and residential exposure to joinery-type products is anticipated to be minimal, a cumulative assessment is not required for these uses.

4.0 Impact on the Environment

Treated wood joinery products are not subject to significant leaching. The treated window frames and doors are either clad with protective aluminum or vinyl, or are top coated with paint or varnish. The finished windows and doors are installed above-ground in buildings that are generally designed to minimize contact with rain. Any leaching of joinery preservative that does occur, should be limited to the area around the building in which they were installed. Therefore, due to limited environmental exposure, no quantitative environmental risk assessment was conducted for the joinery uses of propiconazole. Furthermore, as most joinery active ingredients are also antisapstain active ingredients, the environmental risk assessment for the antisapstain use of propiconazole would be expected to cover any environmental risks posed by joinery products.

4.1 Fate and Behaviour in the Environment

Data on the fate and behaviour of propiconazole and its transformation products in the environment were previously summarized in PRVD2011-02 which included the re-evaluation of the non-antisapstain uses of propiconazole.

Through its use as an antisapstain, propiconazole may enter the environment when it leaches from treated wood that has come in contact with water.

In the terrestrial environment, propiconazole is expected to be slightly persistent to persistent. Biotransformation is an important route of transformation for propiconazole. Major transformation products were found to be 1,2,4-triazole and compounds hydroxylated at the dioxolane moiety. Triazole is moderately persistent in the soil under aerobic conditions. Phototransformation in soil is not an important route of transformation for propiconazole. Propiconazole appears to have a medium to low mobility in soil depending on the soil type. The leaching assessment indicates that propiconazole may have the potential to leach in certain soil

types. In field studies, propiconazole was only detected in the upper soil layers whereas some transformation products have been shown to move as much as 60 cm down into the soil profile.

Propiconazole is very soluble in water, phototransforms slowly and is stable to hydrolysis. Biotransformation is the most likely route of transformation in the aquatic environment. In the aquatic environment, propiconazole appears to be moderately persistent to persistent under aerobic conditions, and persistent under anaerobic conditions. Major transformation products can be either of two compounds which are hydroxylated at the dioxolane moiety. Based on laboratory testing, propiconazole is expected to partition from water to soil or sediment, but this was not observed in available monitoring data.

Volatilization and subsequent phototransformation of propiconazole in air is unlikely due to the low vapour pressure and Henry's law constant. Bioaccumulation of propiconazole is not expected to be a concern in animal tissues or the environment as it depurates from tissues rapidly.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide in the environment.

Environmental exposure from chemicals used to treat wood may result from two scenarios: runoff from wood treatment facilities to adjacent waterbodies or direct leaching from wood in-use to water or soil. Antisapstain products are designed for short-term protection of wood, primarily during its storage and transit. The treated wood is not expected to be in direct contact with soil or water during its use, such as in the construction of above-ground components of various structures. Therefore, only an assessment of the potential environmental exposure from treatment facilities was considered to be relevant for antisapstain products.

At wood treatment facilities using antisapstain products, these chemicals may enter the environment when freshly treated wood is exposed to precipitation (primarily rainwater). Although the wood treatment process itself generally occurs in enclosed areas, immediately after the treatment the wood needs to sit for a short period of time to allow excess treatment solution to drip off the freshly-treated wood and for the wood to dry. This initial drying process is to take place outside on a drip pad that is roofed and paved. This minimizes the exposure of the treated wood to rain, while the paved surface aids in containing the drippings from the wood and channeling any excess chemicals to the appropriate receptacles for recycling or disposal. However, once the treated wood is dry, it is stored at the treatment facility until shipment to retailers and may be exposed to rain. Therefore, there is a potential that when used as an antisapstain, propiconazole may enter the environment through leaching from the treated wood during storage at wood treatment facilities.

Exposure of terrestrial organisms to propiconazole within the vicinity of these storage areas is expected to be negligible. Therefore, the risk to terrestrial organisms was not considered further in the risk assessment. Exposure to aquatic habitats is possible if propiconazole leaches from stored, treated wood at treatment facilities and runs-off to adjacent waterbodies.

The EECs of propiconazole resulting from this use are based on selected exposure scenarios (Appendix II, Table 1), developed from the OECD Revised Emission Scenario Document for Wood Preservatives (OECD, 2013). Scenario selection was based on the following considerations:

Propiconazole is to be applied only by dipping (including immersion) or automated spraying (large plant / small plant) at treatment facilities.

As propiconazole is not expected to volatilize, EECs in air are expected to be negligible. EECs for this compartment are not required.

Exposure of non-target organisms in the terrestrial environment is expected to be minimal.

Environmental exposure to these products when the wood is in use is expected to be limited.

Treatment facilities, including the drip pad for initial drying of treated wood, consist mostly of paved and roofed areas, except for longer-term storage, so leaching of propiconazole from treated wood to soil is expected to be limited to in and around the facilities.

Propiconazole may enter the aquatic environment through leaching from treated wood stored at treatment facilities followed by runoff to nearby waterbodies (either freshwater or marine).

4.2.1 Risks to Aquatic Organisms

The exposure scenario for freshwater and estuarine organisms considers surface runoff into adjacent waterbodies from treatment plants using automated spraying (small plant, scenario 1; large plant, scenario 2) and dipping (scenario 3) product application methods. Conservative scenarios were assumed which supposed that the storage areas were uncovered and unprotected, 100% of the pesticide leached during the storage period, and that 50% of the rainwater ran directly into an adjacent surface water body. Further details for all exposure scenarios are presented in Appendix II, Table 1.

As no data were available for propiconazole leaching from wood, EECs are derived from the specific scenario parameters identified in Appendix II, Table 1 in combination with the deposition rate of the chemical as stated on the label (Appendix II, Table 2). For each scenario, EECs are calculated on a daily basis and consider that 100% of the pesticide leaches during the storage period.

Ecotoxicology information includes acute and chronic toxicity data for various groups of organisms from aquatic habitats (freshwater and marine) including invertebrates, vertebrates, and plants. A summary of the available aquatic toxicity data for propiconazole was previously summarized in PRVD2011-02. Aquatic toxicity values used for this assessment are summarized in Appendix II, Tables 3, 4, and 5.

For characterizing acute risk, acute toxicity values (LC_{50}, LD_{50}, and EC_{50}) are multiplied by an uncertainty factor. The uncertainty factor is used to account for differences in inter- and intra-species sensitivity as well as varying protection goals (community, population, individual). Thus, the magnitude of the uncertainty factor depends on the group of organisms that are being evaluated (0.1 for fish, 0.5 for aquatic invertebrates). The difference in value of the uncertainty factors reflects, in part, the ability of certain organisms at a certain trophic level (feeding position in a food chain) to withstand, or recover from, a stressor at the level of the population. When assessing chronic risk, the NOEC or NOEL is used and an uncertainty factor is not applied.

A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the RQ is then compared to the level of concern (LOC). If the screening level RQ is below the LOC (LOC=1 for aquatic organisms), the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then further characterization of the risk is required. Data derived from monitoring studies may be used in refining a risk assessment. Calculated EECs and RQs for freshwater and marine organisms are located in Appendix II, Table 3 and Table 4, respectively.

Freshwater Invertebrates: For all scenarios, the LOC for exposure to propiconazole was not exceeded for the acute and chronic exposure to freshwater invertebrates. The use of propiconazole is not expected to pose an acute or chronic risk to freshwater invertebrates.

Freshwater Fish and Amphibians: The risk quotient values did not exceed the LOC for fish, for all acute and chronic exposure scenarios. The risk to aquatic life stages of amphibians was assessed based on the generic freshwater environment scenarios, using the most sensitive fish toxicity values as surrogate endpoints (based on the rainbow trout acute toxicity study, and the fathead minnow chronic toxicity study). The risk quotient values for acute and chronic exposure of amphibians to propiconazole did not exceed the LOC. The use of propiconazole is not expected to pose an acute or chronic risk to freshwater fish and amphibians.

Marine Fish: The risk quotient values for chronic toxicity to marine fish did not exceed the LOC for all scenarios. The use of propiconazole is not expected to pose a chronic risk to marine fish.

Freshwater Vascular Plants: For all scenarios, the LOC for exposure to propiconazole was not exceeded for the acute exposure to freshwater vascular plants. The use of propiconazole is not expected to pose an acute risk to freshwater vascular plants.

Freshwater and Marine Algae: The risk quotient values for acute toxicity to the freshwater diatom (*Navicula seminulum*) did not exceed the LOC for surface runoff from either a small spray treatment facility or a dip treatment facility. The risk quotient value did, however, exceed

the LOC when considering acute exposure to runoff from a large spray treatment facility (RQ = 1.4). The risk quotient values for acute toxicity to marine algae did not exceed the LOC for surface runoff from a small spray treatment facility. The risk quotient values did, however, exceed the LOC when considering either acute exposure to runoff from a large spray treatment facility or a dip treatment facility (RQs = 6.4 and 1.2, respectively). These results are based on several conservative assumptions, including that 50% of the pesticide leached reaches the aquatic environment following an average rain pattern and that all of the active ingredient present in/on stored lumber leaches out within the relatively short storage period. The risk quotients would be lower if a fraction of the active ingredient is retained in the wood, which is likely considering that the efficacy period of the active ingredient (2-6 months) is much longer than the storage duration (3-14 days), and that the storage areas could be roofed or treated wood could be wrapped, both of which would prevent or largely reduce leaching from treated wood. Considering this information, the likelihood that algae would be exposed to propiconazole at concentrations causing lasting effects, when used as an antisapstain, is low. To further characterize the risk to freshwater and marine algae, available stormwater runoff monitoring data from two British Columbia treatment facilities that use propiconazole as an antisapstain were examined.

4.2.2 Monitoring Data

Monitoring studies measuring propiconazole concentrations in water and in sediments likely to be affected by lumber treatment sites using Mycostat-P were available. Concentrations of propiconazole in sediments downstream of an antisapstain treatment facility were measured over a three year period (2001 – 2003). In all sediment samples collected, levels of propiconazole were below the level of detection (0.1 µg/g dry weight). Further consideration of these samples, such as the calculation of risk quotients, was not undertaken since the concentrations of propiconazole measured in sediment samples were below the level of detection.

Over the course of the same three years (2001–2003), samples of stormwater runoff were collected from two British Columbia treatment facilities that use Mycostat-P, an end-use product containing propiconazole. Samples were collected from catch basins collecting the runoff from the mill property and the outfall at the receiving environment. The measured stormwater runoff concentrations ranged from below the level of detection (0.010 mg/L) to 0.400 mg/L and averaged 0.08 mg/L. For catch basins, it is expected that levels would be reduced (by transformation or adsorption to sediments) before release at the outfall. In both sampling scenarios, it is expected that the effluent will be further diluted by the receiving environment(marine estuary or river). In previous scientific evaluations by Health Canada, in order to account for the expected dilution, a generic dilution factor of 10 was applied to the measured concentrations. The generic dilution factor of 10 is affected by many variables including volume, flow rates and mixing characteristics of the receiving water body. Risk quotient values were calculated using all toxicity endpoints in combination with the maximum measured concentration of propiconazole with the 10-fold dilution factor applied (Appendix II, Table 5). Using these values, concentrations of propiconazole found in stormwater runoff were below the level of concern for all representative test species except for marine algae (RQ = 3.8).

Although the absolute peak value was not necessarily captured in the monitoring data, it is considered representative of the highest expected risk to marine algae, which would only occur sporadically and for a brief period of time, following rain events sufficient for the catch basins to overflow.

Risk to marine algae was further characterized using the average measured concentration with the 10-fold dilution factor (resulting in an EEC of 0.008 mg/L). Based on this refined risk assessment, the LOC was not exceeded for marine algae (RQ = 0.76; Appendix II, Table 5).

4.2.3 Overall Summary

The results of the risk assessment based on the measured maximum value from monitoring data (Section 4.2.2) are similar to the results of the risk assessment based on exposure scenarios developed from the OECD Emission Scenario Document for wood preservatives (Section 4.2.1). Risk quotient values only slightly exceed the level of concern for algae. When further characterizing the risk to marine algae using the average measured values from monitoring data, the LOC is no longer exceeded.

Considering the conservatisms of the risk assessment, as described in Sections 4.2.1 and 4.2.2, and the propensity of algal species to reproduce rapidly and have new algae populations be introduced (by tidal flushing, river flow, wind-induced currents, or vertical mixing, as well as other mechanisms), it can be concluded that the use of propiconazole as an antisapstain or for joinery is not expected to pose risks of concern to the environment.

4.2.4 Incident Reports

As of 14 September 2015, the PMRA has received one environment incident involving the active ingredient propiconazole.

In this incident, fire douse water, used to control a pesticide warehouse fire, flowed into a nearby creek resulting in fish mortality. Several pesticides including propiconazole were detected in the fire douse water. It was concluded that the various pesticides found in the fire douse water may have caused the fish mortality.

The incident report data were considered in this evaluation and did not affect the risk assessment.

5.0 Value

Antisapstains

Propiconazole has value as one of several antisapstain active ingredients that are options for controlling sapstain. It is important to have a number of different options to ensure availability and product rotation. The current active ingredients have replaced older antisapstain chemistries based on chlorophenates, which were phased-out in the 1980's for this use due to health and environmental concerns.

The application rates of antisapstain products are expressed both as treatment solution concentrations (%) and as the deposition rate in the treated wood (for example, µg a.i. per cm^2 wood). They are applied to freshly-cut wood in saw mills by dipping or spraying to achieve a short-term protection of several months. An alternative to antisapstain treatment is kiln-drying of the wood. However, some freshly cut lumber may still require antisapstain treatment while it is stored prior to kiln drying.

Joinery

Propiconazole has value as one of several joinery active ingredients that are options to protect millwork. It is valuable to have a number of different options to ensure product availability and product rotation. The current active ingredients have replaced older joinery chemistries based on tributyltin and organic mercury-based products, which were discontinued in the 1990's due to health and environmental concerns. Joinery products are typically applied by dip and spray, but may also be applied to wood with flood coating or double vacuum treatment. The application rates of joinery products are expressed as treatment solution concentrations (%) and as either a deposition rate (µg a.i. per cm^2 wood surface) or a retention rate (kg a.i. per m^3 wood volume) in the treated wood.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act, 1999*].

Propiconazole and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[6] and evaluated against the Track 1 criteria during the re-evaluation of the agricultural, turf and remedial wood preservative uses of propiconazole. Refer to Section 5.1 of PRVD2011-02 for the conclusions reached by the PMRA on this subject as well as Table 3.7 (Appendix V of PRVD2011-02) for a comparison of propiconazole with Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[7]. The list

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6 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

7 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order

is used as described in the PMRA Notice of Intent NOI2005-01[8] and is based on existing policies and regulations including DIR99-03 and DIR2006-02,[9] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Propiconazole does not contain any formulants of health or environmental concern identified in the *Canada Gazette*.

The end-use products Mycostat-P, Woodtreat P-229, Mycostat P20 Wood Preservative Treatment, Mycostat-MX, Mycostat PQ and Antiblu TK-30 do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Proposed Re-evaluation Decision

The PMRA is proposing that antisapstain and joinery uses of products containing propiconazole are acceptable for continued registration with additional risk-reduction measures to protect human health and the environment. The proposed mitigation measures are presented in Appendix III. No additional data are being requested at this time.

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amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

8 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New Pest Control Products Act.

9 DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

List of Abbreviations

ADI	acceptable daily intake
AFC	antibody forming cell
ai	active ingredient
ALB	albumin
ALP	alkaline phosphatase
ALT	alanine aminotransferase
ARfD	acute reference dose
AST	aspartate aminotransferase
BUN	blood urea nitrogen
bw	body weight
bwg	bodyweight gain
CHO	Chinese hamster ovary
cm	centimetre(s)
d	day(s)
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
EC_{50}	effective concentration on 50% of the population
EEC	estimated environmental concentration
ERP	Exposure Reduction Program
EU	European Union
F_1	first generation
F_2	second generation
fc	food consumption
FOB	functional observation battery
g	gram(s)
GD	gestation day
GI	gastrointestinal
h	hectare(s)
HC	historical control
Hct	hematocrit
Hgb	hemoglobin
IgM	Immunoglobulin type M
kg	kilogram(s)
L	litre(s)
LOC	level of concern
LC_{50}	lethal concentration to 50%
LD	lactation day
LD_{50}	lethal dose to 50%
LDH	lactate dehydrogenase
m	meter(s)
MAS	maximum average score
mg	milligram(s)
MIS	mean irritation score
mL	millilitre
MMAD	mass median aerodynamic diameter

MOE	margin of exposure
MTD	maximum tolerated dose
N/A	not applicable
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
P	parental generation
ppb	parts per billion
PMRA	Pest Management Regulatory Agency
PND	postnatal day
ppm	parts per million
RBC	red blood cells
RQ	risk quotient
s	second(s)
SIG	Sapstain Industry Group
SRBC	sheep red blood cells
TGAI	technical grade active ingredient
TSC	treatment solution concentration
TSMP	Toxic Substances Management Policy
wks	weeks
wt(s)	weight(s)
WBC	white blood cells
µg	microgram
µL	microlitre

Appendix I

Table 1 Antisapstain Propiconazole Products Currently Registered

Active	Technical Grade Active Ingredient Sources		End-Use Products	
	Registration Number	Product Name	Registration Number	Product Name
Propiconazole	22474	Wocosen Technical	26500	Mycostat-P Sapstain Control Chemical
			26584	Wocosen 250 EC Sapstain Chemical
	24515		27136	Mycostat P20
		Wocosen 50TK Manufacturing Concentrate	29407 (co-formulated with DDAC)	Mycostat PQ Wood Preservative Treatment
			29224	Mycostat-MX
			29547	Antiblu® TK-30

Table 2 Joinery Propiconazole Products Currently Registered

Active	Technical Grade Active Ingredient Sources		End-Use Products	
	Registration Number	Product Name	Registration Number	Product Name
Propiconazole	22474	Wocosen Technical	24134	Wocosen S
	24514	Wocosen 100SL	24135	Wocosen WR
	24515	Wocosen 50TK Manufacturing Concentrate	24514	Wocosen 100SL
			30584 (co-formulated with Iodocarb & tebuconazole)	Woodlife 111 Water Repellent Wood Preservative
	30798	Preventol A12	29484	Woodtreat 100
	30800	Preventol A12 TK-50	24246	Dryvac 1010 Water Repellent Wood Preservative

Appendix II

Table 1 Scenarios Considered for the Environmental Risk Assessment

Scenario	Description	Details	
Scenario for industrial preventive treatment			
	Runoff from storage of treated wood		
1	**Automated spraying (small plant)**	Surface area of the storage place: Exposed surface of wood: Duration of storage: Rain fraction reaching water: Flow rate of creek/river:	79 m^2 11 $m^2_{wood}/m^2_{storage\ area}$ 3 d 0.5 0.3 m^3s^{-1}
2	**Automated spraying (large plant)**	Surface area of the storage place: Exposed surface of wood: Duration of storage: Rain fraction reaching water: Flow rate of creek/river:	790 m^2 11 $m^2_{wood}/m^2_{storage\ area}$ 3 d 0.5 0.3 m^3s^{-1}
3	**Dipping/Immersion**	Surface area of the storage place: Exposed surface of wood: Duration of storage: Rain fraction reaching water: Flow rate of creek/river:	700 m^2 11 $m^2_{wood}/m^2_{storage\ area}$ 14 d 0.5 0.3 m^3s^{-1}

Table 2 Amount of Propiconazole Leached from Freshly Treated Wood

Scenario	Deposition rate ($\mu g/m^2$)[a]	Surface area of the storage place (m^2)	Exposed surface of wood ($m^2_{wood}/m^2_{storage\ area}$)	Storage Period (d)	Amount of propiconazole leached (kg/d)[b,c]
Automated spraying (small plant)	600 000	79	11	3	0.17
Automated spraying (large plant)	600 000	790	11	3	1.74
Dipping/Immersion	600 000	700	11	14	0.33

[a]Highest deposition rate of propiconazole from all antisapstain products currently registered by the PMRA and confirmed by VRD.
[b]Amount of propiconazole leached = Deposition rate * Surface area of the storage place * Exposed surface of wood / Storage period.
[c]Emissions from a storage facility are considered stable over time and assume that 100% of the pesticide leaches during the storage period.

Table 3 Expected Environmental Concentrations (EECs) and Risk Quotients (RQs) for Freshwater Organisms Based on Storage of Treated Wood (Surface Runoff from Treatment Facilities)

Organism	Species Uncertainty Factor	Endpoint[1]			1-d EEC[2] (mg a.i./L)	RQ[3]
Storage after automated spraying (small plant)						
Daphnia magna	1/2	48-h LC_{50}	= 1.1	mg a.i./L	0.0067	0.006
		21-d NOEC	= 0.31	mg a.i./L	0.0067	0.022
Rainbow trout	1/10	96-h LC_{50}	= 0.085	mg a.i./L	0.0067	0.079
Fathead minnow		NOEC	= 0.095	mg a.i./L	0.0067	0.071
Diatom	1/2	11-d EC_{50}	= 0.0465	mg a.i./L	0.0067	0.144
Duckweed	1/2	EC_{50}	= 2.414	mg a.i./L	0.0067	0.003
Hyalella azteca	1/2	14-d LC_{50}	= 1.78	mg a.i./L	0.0067	0.004

Chironomid		28-d NOEC	= 2.0	mg a.i./L	0.0067	0.002
Storage after automated spraying (large plant)						
Daphnia magna	1/2	48-h LC_{50}	= 1.1	mg a.i./L	0.0671	0.061
		21-d NOEC	= 0.31	mg a.i./L	0.0671	0.216
Rainbow trout	1/10	96-h LC_{50}	= 0.085	mg a.i./L	0.0671	0.789
Fathead minnow		NOEC	= 0.095	mg a.i./L	0.0671	0.706
Diatom	1/2	11-d EC_{50}	= 0.0465	mg a.i./L	0.0671	**1.442**
Duckweed	1/2	EC_{50}	= 2.414	mg a.i./L	0.0671	0.028
Hyalella azteca	1/2	14-d LC_{50}	= 1.78	mg a.i./L	0.0671	0.038
Chironomid		28-d NOEC	= 2.0	mg a.i./L	0.0671	0.017
Storage after dip/immersion						
Daphnia magna	1/2	48-h LC_{50}	= 1.1	mg a.i./L	0.0127	0.012
		21-d NOEC	= 0.31	mg a.i./L	0.0127	0.041
Rainbow trout	1/10	96-h LC_{50}	= 0.085	mg a.i./L	0.0127	0.150
Fathead minnow		NOEC	= 0.095	mg a.i./L	0.0127	0.134
Diatom	1/2	11-d EC_{50}	= 0.0465	mg a.i./L	0.0127	0.274
Duckweed	1/2	EC_{50}	= 2.414	mg a.i./L	0.0127	0.005
Hyalella azteca	1/2	14-d LC_{50}	= 1.78	mg a.i./L	0.0127	0.007
Chironomid		28-d NOEC	= 2.0	mg a.i./L	0.0127	0.003

[1]Endpoints used in the acute exposure risk assessment are derived by multiplying the EC_{50} or LC_{50} from the appropriate laboratory study by the species uncertainty factor.
[2]Expected Environmental Concentration (EEC) = amount of propiconazole leached per day (Table 2) / flow rate of a creek or river (Table 1). EECs are calculated on a per day basis.
[3]Risk Quotient (RQ) = exposure/toxicity. RQ > 1 (in bold) indicates exceedance of LOC (Level Of Concern).

Table 4 Expected Environmental Concentrations (EECs) and Risk Quotients (RQs) for Marine Organisms Based on Storage of Treated Wood (Surface Runoff from Treatment Facilities)

Organism	Species Uncertainty Factor	Endpoint[1]			1-d EEC[2] (mg a.i./L)	RQ[3]
Storage after automated spraying (small plant)						
Sheepshead minnow		NOEC	= 0.15	mg a.i./L	0.0067	0.045
Marine algae	1/2	11-d EC_{50}	= 0.0105	mg a.i./L	0.0067	0.639
Storage after automated spraying (large plant)						
Sheepshead minnow		NOEC	= 0.15	mg a.i./L	0.0671	0.447
Marine algae	1/2	11-d EC_{50}	= 0.0105	mg a.i./L	0.0671	**6.386**
Storage after dip/immersion						
Sheepshead minnow		NOEC	= 0.15	mg a.i./L	0.0127	0.085
Marine algae	1/2	11-d EC_{50}	= 0.0105	mg a.i./L	0.0127	**1.213**

[1]Endpoints used in the acute exposure risk assessment are derived by multiplying the EC_{50} or LC_{50} from the appropriate laboratory study by the species uncertainty factor.
[2]Expected Environmental Concentration (EEC) = amount of propiconazole leached per day (Table 2) / flow rate of a creek or river (Table 1). EECs are calculated on a per day basis.
[3]Risk Quotient (RQ) = exposure/toxicity. RQ > 1 (in bold) indicates exceedance of LOC (Level Of Concern).

Table 5 Expected Environmental Concentrations and Risk Quotients for Freshwater and Marine Organisms Based on 10-fold Dilution of Stormwater Runoff Monitoring Data from Two Mycostat-P Treatment Facilities 2001– 2003

Organism	Species Uncertainty Factor	Endpoint[1]			1-d EEC (mg a.i./L)	RQ[2]
Freshwater organisms						
Daphnia magna	1/2	48-h LC_{50}	= 1.1	mg a.i./L	0.04[3]	0.036
		21-d NOEC	= 0.31	mg a.i./L	0.04[3]	0.129
Rainbow trout	1/10	96-h LC_{50}	= 0.085	mg a.i./L	0.04[3]	0.471
Fathead minnow		NOEC	= 0.095	mg a.i./L	0.04[3]	0.421
Diatom	1/2	11-d EC_{50}	= 0.0465	mg a.i./L	0.04[3]	0.860
Duckweed	1/2	EC_{50}	= 2.414	mg a.i./L	0.04[3]	0.017
Hyalella azteca	1/2	14-d LC_{50}	= 1.78	mg a.i./L	0.04[3]	0.022
Chironomid		28-d NOEC	= 2.0	mg a.i./L	0.04[3]	0.010
Marine organisms						
Sheepshead minnow		NOEC	= 0.15	mg a.i./L	0.04[3]	0.267
Marine algae	1/2	11-d EC_{50}	= 0.0105	mg a.i./L	0.04[3]	**3.810**
Marine algae	1/2	11-d EC_{50}	= 0.0105	mg a.i./L	0.008[4]	0.762

[1]Endpoints used in the acute exposure risk assessment are derived by multiplying the EC_{50} or LC_{50} from the appropriate laboratory study by the species uncertainty factor.
[2]Risk Quotient (RQ) = exposure/toxicity. RQ > 1 (in bold) indicates exceedance of LOC (Level Of Concern).
[3]Expected Environmental Concentration (EEC) = maximum concentration detected in stormwater runoff (0.4 mg a.i./L) / generic dilution factor of 10 (Health Canada, 2000).
[4]Expected Environmental Concentration (EEC) = mean concentration detected in stormwater runoff (0.08 mg a.i./L) / generic dilution factor of 10 (Health Canada, 2000).

Appendix III Label Statements Required for Antisapstain and Joinery Products containing Propiconazole

PROPOSED STATEMENTS TO PROTECT HUMAN HEALTH

To protect workers, additional personal protective equipment is required on all propiconazole antisapstain and joinery product labels. Label statements must be amended (or added) to include the following statements in a section entitled **PRECAUTIONS** to the appropriate labels:

Antisapstain Product Labels

- Wear chemical-resistant coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, goggles or face shield, socks, and chemical-resistant footwear when handling the concentrate or during mixing/loading, application, clean-up, maintenance and repair activities.
- Use a NIOSH-respirator if the area is not well ventilated and during clean-up, maintenance and repair activities.
- When piling freshly treated lumber or if there is a potential for getting wet by the treating solution or by handling freshly treated lumber, wear chemical-resistant coveralls or a chemical-resistant apron over long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear.
- When working in the dip or spray area, wear long-sleeved shirt, long pants, chemical-resistant gloves, socks and boots. Wear goggles or face shield if there is a possibility of splashing.
- Once dry, the treated wood can be handled with cotton or leather gloves.
- Wash hands and face before eating, drinking, smoking and using the toilet. Change clothes daily. Wash contaminated clothing separately from household laundry. Not for use or storage in or around the home. Clean contaminated equipment thoroughly prior to making welding repairs.

Joinery Product Labels:

The following personal protective equipment is required on all joinery product labels to reduce potential exposure:

- Wear chemical-resistant coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, goggles or face shield, socks, and chemical-resistant footwear when handling the concentrate or during mixing/loading, application, clean-up, maintenance and repair activities.
- Use a NIOSH-respirator if the area is not well ventilated and during clean-up, maintenance and repair activities and when opening pressure treatment cylinder doors.
- When handling freshly treated lumber or if there is a potential for getting wet by the treating solution, wear chemical-resistant coveralls or a chemical-resistant apron over long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear.
- When working in the application area, wear long-sleeved shirt, long pants, chemical-resistant gloves, socks and boots. Wear goggles or face shield if there is a possibility of splashing.

- Once dry, the treated wood can be handled with cotton or leather gloves.
- Wash hands and face before eating, drinking, smoking and using the toilet. Change clothes daily. Wash contaminated clothing separately from household laundry. Not for use or storage in or around the home. Clean contaminated equipment thoroughly prior to making welding repairs.

PROPOSED ENVIRONMENTAL STATEMENTS

A. Environmental Label statements required for TGAIs: Wocosen Technical, Wocosen 50TK Manufacturing Concentrate, Propibio 50 MC, and Preventol A12 TK-50

I) The following statements are required in an " **ENVIRONMENTAL HAZARDS**." section:

TOXIC to aquatic organisms.

"**DO NOT** discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters."

II) The following statement is required in a "DISPOSAL" section:

Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and clean-up of spills, contact the manufacturer or the provincial regulatory agency.

B. Environmental Label statements required for End Use Products: Mycostat-P, Woodtreat P-229, Mycostat P20 Wood Preservative Treatment, Mycostat-MX, Mycostat PQ, and Antiblu TK-30

I) The following statement is required in an " **ENVIRONMENTAL HAZARDS**." section:

TOXIC to aquatic organisms.

II) The following statements are required in a "DIRECTIONS FOR USE": section:

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters unless the effluent has been detoxified by suitable means.

Dip tanks and drip aprons must be roofed, paved and drained to prevent dilution and loss of treatment solution.

Store treated lumber on a roofed drip pad until dripping has ceased. Slope lumber on the drip pad to expedite drainage and to ensure that no puddles remain on the surface of the wood. Manage drippage and other related wastes to prevent release in the environment.

DO NOT expose treated lumber to rains immediately after treatment.

For further information on storage, handling, and disposal of treated wood, contact the manufacturer of this product or the provincial regulatory agency.

III) The following statement is required in a "STORAGE" section:

To prevent contamination store this product away from food or feed.

IV) The following statement is required in a "DISPOSAL" section:

DO NOT reuse this container for any other purpose. This is a recyclable container, and is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site. Before taking the container to the collection site:

1. Triple- or pressure-rinse the empty container. Dispose of the rinsings in accordance with provincial requirements.

2. Make the empty, rinsed container unsuitable for further use.

If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.

For information on disposal of unused, unwanted product, or in the case of a spill or spill clean-up, contact the manufacturer or the provincial regulatory agency.

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